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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,531	12/14/2001	Sukhendu B. Dev	GENE1180-2	1163

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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3763

#9

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/020,531

Applicant(s)

DEV ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 29, 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-5, 7-14 and 16-21 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al., 5,505,700.

Leone et al. discloses the invention substantially as claimed. More specifically, Leone et al. discloses a catheter (11) having at least one inflatable balloon portion (16 and 17), wherein upon inflation, the balloon occludes the vessel ; at least one infusion opening (19) for introducing the composition into the subject proximal to the at least one inflatable balloon portion ; a first electrode (35) positioned adjacent to at least one infusion opening ; and a second electrode (36) positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell after introduction of the composition through at least one infusion opening, see column 4, lines 49-63.

Specifically with respect to Claims 3, 12 and 19, the vessel is a blood vessel (22).

As to claims 4, 13 and 20, the first electrode (35) is formed at least in part by a biologically inert material, see column 4, lines 56-57.

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As to claims 5, 14 and 21, the second electrode is a guidewire in the catheter, see column 4, line 63.

As to claim 7, the catheter has two inflatable balloon portions (16 and 17).

As to claim 8, the at least one infusion opening (19) is between the two inflatable balloon portions (16 and 17), see Figure 2.

As to claim 9, the first electrode (35) is coincident with the at least one infusion opening (19).

As to claims 10 and 17, Leone et al. discloses a first inflatable balloon portion (17) near the distal end of the catheter; a second inflatable balloon portion (16) proximal the first inflatable balloon, wherein inflation of the first and second balloon occludes a vessel (22) between the first and second balloon; at least one infusion opening (19) for introducing a composition into a subject located between the first and second balloon portions; a first electrode (35) positioned adjacent to or integral with at least one infusion opening; and a second electrode (36) positioned with respect to the first electrode and the subject such that an electric field sufficient to cause electroporation of at least one cell before, during or after introduction of the composition through the at least one infusion opening, see column 4, lines 49-63.

As to claim 11, an electrical source (15) connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell is disclosed.

As to claim 16, the at least one inflatable balloon (16 or 17) is near the distal end of the catheter.

As to claim 18, an electrical source (15) is connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

As to claim 23, 25 and 27, the first and second electrode is separately selected to be a single electrode or multiple electrodes, see column 4, lines 57-59.

As to claims 24, 26 and 28, the multiple electrodes are interdigitated electrodes or concentric ring electrodes, see column 4, lines 63-67.

However, Leone et al. does not specifically disclose that the first and second electrodes are suitable to receive an electric pulse having an electroporating voltage in the range of about 10 Volts and having a pulse length of about 100 microseconds to 100 milliseconds, and wherein said second electrode is proximally positioned such that when the electric pulse is applied to the first and second electrodes an electric field is generated in the subject of between 0.5 and 5.0 kV/cm, which is sufficient to cause electroporation of at least one cell in the vessel before, during or after introduction of the composition in the subject.

Leone et al. however does teach that the invention can also be used to effect drug release by electroporation, see column 7, lines 39-44. Thus, since Leone et al. teaches that the invention can be used for electroporation, it would have been obvious to adjust the Leone et al. device such that the device is capable of receiving an electric pulse having an electroporating voltage as specifically claimed, and having a pulse length as claimed, and wherein the electric field is generated as claimed.

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Claim 6, 15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al., 5,505,700, in view of Shapland et al., 5,634,899.

Leone et al. discloses the invention substantially as claimed, see above. However, Leone et al. does not disclose that the second electrode is a silver plate configured to be placed in contact with the subject. Leone et al. however does teach that the electrodes (35 and 36) may take on the configurations as disclosed or may take on additional or alternate configurations, see column 4, lines 63-66.

Moreover, Shapland et al. teaches that electroportion is employed by use of a catheter electrode located on or within the catheter body, and a remote electrode, see column 5, lines 44-46. Shapland teaches that preferred electrode materials include silver, see column 5, lines 55-63. Shapland discloses that the invention includes a delivery means that include a permeable membrane to control transport a drug therethrough, and uses current/voltage means to transport the drugs, see column 3, lines 5-24. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Shapland teaches to utilize silver as the second electrode in the Leone et al. invention, as a substitute material and configuration.

Response to Arguments

Applicant's arguments filed October 29, 2002 have been fully considered but they are not persuasive.

Applicant argues that Leone et al. is silent with respect to the device having an electric pulse having an electroporating voltage as specifically claimed, and having a pulse length as claimed, and wherein the electric field is generated as claimed. In response, Examiner points out that Leone et al. teaches that the invention can be used to effect drug release by electroporation, see column 7, lines 39-44, and thus it would have been obvious to adjust the Leone et al. device such that the device is capable of receiving an electric pulse having an electroporating voltage as specifically claimed, and having a pulse length as claimed, and wherein the electric field is generated as claimed.

As to claims 6, 15 and 22, Examiner reasserts that it would have been obvious to use the Shapland teaches to utilize silver as the second electrode in the Leone et al. invention, as a substitute material and configuration, as described in the above rejection.

Applicant also argues that the reference does not describe use of a guidewire as an electrode. Examiner reasserts that the second wire is a guidewire, see column 4, line 63. More specifically, wire (35) is considered a guidewire in the catheter, see Figure 2, where wire (35) enters the catheter, or column 5, lines 44-48, which discloses wire (45) entering the catheter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

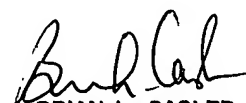
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.

January 26, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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